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NOTES:

U.S. Serial No.: 09/864,083, Filed May 23, 2001

Inventors: Wortzman, et al.

Title: COMPOSITIONS FOR THE TREATMENT OF PIGMENTATION DISORDERS AND METHODS FOR THEIR MANUFACTURE

Attorney Docket.: 01-40076-US

Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Wortzman, Gordon, Gans, Patel

Serial No.: 09/864,083

Filed: May 23, 2001

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE TREATMENT
OF PIGMENTATION DISORDERS AND
METHODS FOR THEIR MANUFACTURE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S INTERVIEW SUMMARY

Sir:

Applicant hereby submits this Interview Summary regarding the interview with Examiner Kim, and Applicant's attorneys Maryellen Feehery and Edward Behm on February 24, 2004.

Claims 1-23 and the cited references (Gordon U.S. Patent No. 5,932,612 "Gordon" and Lukenbach U.S. Patent No. 5,980,871 "Lukenbach") were discussed. The Declaration by Philip J. Gordon, filed on October 23, 2003, was also discussed.

Applicant's attorneys clarified for the Examiner that Benjamin Gordon, the inventor of U.S. Patent No. 5,932,612, is not Philip J. Gordon, an inventor of the present invention.

Applicant's attorneys pointed out that neither Lukenbach nor Gordon addresses problems solved by the present invention, including the discoloring and/or oxidation of the composition, nor teaches the advantages of the present invention. Applicant submits that the stability of Applicant's composition is a result unexpected by those skilled in the art. Applicant respectfully

submits Lukenbach in conjunction with Gordon, fails to teach a cosmetically acceptable, stable combination of hydroquinone and a cationic salt of acidic ascorbyl esters having a pH of about 5.5 to about 8.0, a problem addressed by the present invention. Applicant's attorneys called the Examiner's attention to the Declaration by Philip J. Gordon, filed October 23, 2003, a named inventor, which pointed out that in actual preparation of Lukenbach's Example compositions, one containing magnesium ascorbyl phosphate and one containing hydroquinone, both at a pH of 7.5, there is discoloration. Neither Lukenbach Example was stable. Given that the experimental data presented in the Gordon Declaration showed that Lukenbach's Examples were unstable at 7.5 pH, Applicant's attorneys argued that one of ordinary skill in the art would not expect a composition with both active ingredients, hydroquinone and magnesium ascorbyl phosphate (a cationic salt of acidic ascorbyl esters), at 7.5 pH to be stable. Further, Applicant even provided three examples of U.S. patents (attached as Exhibit A hereto) which teach that compositions containing less than four percent (4%) hydroquinone (as permitted by the Food and Drug Administration) are stably prepared in a pH range of 3.3 – 4.0. *See, e.g.*, United States Patent No. 5,889,054, column 7, lines 54-56 and column 13, lines 19-21. Additionally, Gordon does not teach a pH for the compositions. From the Lukenbach examples and the pH known for hydroquinone stable compositions (see Applicant's Exhibit A), one of ordinary skill in the art would never try to prepare Gordon at Applicant's specified pH range.

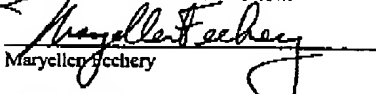
The Examiner was reminded that she has failed to provide express support for her assertion that one of ordinary skill in the art would prepare Gordon's compositions in Applicant's claimed pH range. (See Paper 15, page #3). Applicant's attorneys again requested that the Examiner support this position with documentary evidence or her own sworn declaration, as is

required by 37 C.F.R. § 1.104(d)(2). At the interview, the Examiner declined to do so, and indicated that such evidence or declaration would not be provided.

Examiner Kim proposed that the claims be amended to include "method claims." Additionally, the Examiner proposed that the claims be amended to claim a buffer or buffer system consistent with the claimed pH range.


Applicant does not believe any fee is required for this Interview Summary, however, in the event any fee is required, the Commissioner is authorized to charge Deposit Account No. 18-0586.

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March 10, 2004

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Respectfully submitted,


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